# THE LEGISLATIVE ASSEMBLY FOR THE AUSTRALIAN CAPITAL TERRITORY

# **ELEVENTH ASSEMBLY**

# **ASSISTED REPRODUCTIVE TECHNOLOGY AMENDMENT BILL 2025**

EXPLANATORY STATEMENT and
HUMAN RIGHTS COMPATIBILITY STATEMENT (Human Rights Act 2004, s 37)

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# ASSISTED REPRODUCTIVE TECHNOLOGY AMENDMENT BILL 2025

The Bill **is not** a Significant Bill. Significant Bills are bills that have been assessed as likely to have significant engagement of human rights and require more detailed reasoning in relation to compatibility with the *Human Rights Act 2004*.

This explanatory statement relates to the *Assisted Reproductive Technology Amendment Bill 2025* (**Bill**) as presented to the Legislative Assembly. It has been prepared to assist the reader of the Bill and to help inform debate on it. It does not form part of the Bill and has not been endorsed by the Assembly. The statement is to be read in conjunction with the Bill. It is not, and is not meant to be, a comprehensive description of the Bill.

#### **OVERVIEW OF THE BILL**

The Bill amends the Assisted Reproductive Technology Act 2024 (ART Act). The primary purpose of the Bill is to expand the transitional provisions in Part 12 of the ART Act to a new cohort of people. This new cohort comprises people who were allocated gametes prior to 28 September 2024 (the end of the transitional period for the ART Act), and for whom use of those gametes now does not comply with the requirements established by the ART Act.

The Bill largely enables this new cohort of people to use these allocated gametes for ART treatment, by exempting the use of these gametes from the operation of certain provisions of the ART Act. The Bill will also ensure that individuals who became pregnant prior to 28 September 2024 or who created embryos prior to 28 September 2024 (the end of the transitional period for the ART Act) are able to complete their families using newly acquired gametes from the same donor.

A number of technical amendments are also included in the Bill to ensure the effective operation of the ART Act.

#### The ART Act

The ART Act introduced regulatory requirements for the clinical practice of Assisted Reproductive Technology (**ART**) by ART providers, including registration requirements, requirements around provision of clinical services and requirements for gamete retrieval, embryo creation, storage and disposal. Of relevance, the ART Act:

- requires that certain information about a donor be collected by an ART provider prior to obtaining or using the donor's gametes for ART treatment (section 46);
- places limits on the number of families that can be created from one donor ('family limits'), to place an acceptable limit on how many siblings a donorconceived person may have, which will also assist in reducing the likelihood of

- a person unknowingly forming a consanguineous relationship with a sibling or close relative (section 40); and
- provides for the establishment of a register of donor gametes or embryos, containing information in relation to donors (the person/s donating sperm, eggs or an embryo), intended parent(s) who receive the donation, and the donor-conceived person born because of the donation (donor register) (Part 5).

Since 2004, in order to be accredited by the Reproductive Technology Accreditation Committee of the Fertility Society of Australia and New Zealand (Fertility Society), ART providers in Australia have had to comply with the National Health and Medical Research Council *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research* (NHMRC Guidelines). All existing ART providers in the Territory are accredited by the Fertility Society and, in order to maintain their accreditation, ART providers in the ACT are required by the Fertility Society to comply with the NHMRC Guidelines.

Following commencement of the ART Act, ART providers in the ACT must comply with both the legislation *and* the NHMRC Guidelines. The regulatory aspects of the ART Act were designed to complement the NHMRC Guidelines and enshrine in law clinical and ethical obligations which are largely already required by the NHMRC Guidelines. Although the proposed amendments exempt an additional small cohort of people from some provisions of the ART Act under expanded transitional provisions, this does not result in a complete lack of regulation—ART providers will still be required to comply with the NHMRC Guidelines to maintain their accreditation, including, for example:

- Requirements about keeping records and allowing donor conceived people
  access to information about gamete donors, including medical history, family
  history, genetic tests relevant to the future health of donor-conceived people or
  their offspring, physical characteristics of the donor, and the number, age and sex
  of persons already born from the gametes provided by the same gamete donor
  and the number of families involved.
- Requirements about taking reasonable steps to minimise the number of families created from one donor, including taking into account: the number of persons already born from the donor's gametes, the risk of consanguineous relationships, family limits consented to by the donor, and whether the donor has already donated gametes at another clinic.

The ART Act has a staged commencement. Most of the provisions have already commenced, either on 29 March 2024 or 28 September 2024. Provisions relating to the donor register (Part 5) will commence 28 March 2025.

The transitional provisions under Part 12 of the ART Act are tied to these commencement dates – with the 'transitional period' (see section 128 of the ART Act) starting from 29 March 2024 and ending on 27 September 2024.

# Amendments to Part 12 (Transitional) of the ART Act

The new arrangements are intended to extend the operation of the ART Act's transitional provisions to a broader group of people. The arrangements operate by exempting the use of gametes or embryos for ART treatment in particular circumstances from either the 'basic provisions' or the 'extended provisions'. The basic provisions are a group of regulatory provisions which commenced on 28 September 2024 and include time limits on use of gametes (section 39), limits on the number of families created (section 40) and the obligation on ART providers to provide mandatory information to the register (section 53) (see new definition of basic provisions at clause 7 of the Bill). The extended provisions include the basic provisions, but also include certain obligations which commenced on 29 March 2024 requiring providers to collect information about gamete providers (section 46) and people receiving ART treatment (section 47) and to keep that information as a record (section 48) (see new definition of extended provisions at clause 7 of the Bill).

The intended effects of the proposed amendments under the Bill are as follows.

- Permit people who were allocated gametes prior to 29 March 2024, which now do
  not comply with the ART Act, to use those gametes for ART treatment without the
  extended provisions applying. If the person becomes pregnant using those
  allocated gametes, the extended provisions will also not apply to the use of
  gametes from the same donor by that person or their domestic partner for
  subsequent pregnancies.
- Permit people who were allocated gametes between 29 March 2024 and 27 September 2024 (transitional period), to use those gametes for ART treatment, without the basic provisions applying. If the person becomes pregnant using those allocated gametes, the basic provisions will also not apply to the use of gametes from the same donor by that person or their domestic partner for subsequent pregnancies.
- If use of gametes in ART treatment results in a pregnancy prior to 28 September 2024, allow the individual who became pregnant or their domestic partner to use gametes from the same donor to complete their families without the extended provisions applying. Note that this applies irrespective of whether the pregnancy results in the birth of a live child.
- Remove the existing requirement in section 131 that the gamete must have been donated before the end of the transitional period.

 If an embryo is created prior to the end of the transitional period, permit the use of that embryo for ART treatment without the extended provisions applying. If the person becomes pregnant using such an embryo, the extended provisions will also not apply to the use of gametes from the same donor by that person or their domestic partner to create and use further embryos.

Note that there will be some overlap between the different transitional arrangements. For example, a person may be permitted under section 131 to use gametes for future pregnancies, and also permitted to use gametes which were allocated before the end of the transitional period under new section 132B or 132C. It is intended that such a person would be able to take the benefit of whichever provision affords that individual the most flexibility.

The current transitional provisions under Part 12 of the ART Act enable individuals who have already started their families to complete their families using gametes obtained from the same donor, even if those gametes do not comply with some of the new requirements introduced under the ART Act. However, for the use of allocated gametes, the transitional provisions as currently set out in the ART Act only apply to people who had already become pregnant using gametes from a donor (section 131) prior to 28 September 2024. These existing transitional provisions do not include people who were already allocated gametes, but who have not yet commenced ART treatment or achieved pregnancy. The current transitional provisions have separate requirements in relation to the use of embryos created prior to 28 September 2024 (section 132 of the ART Act). However, section 132 as currently set out in the ART Act only applies to the use of embryos created prior to this date, and does not permit the completion of a family using gametes from the same donor once the stored embryos have been used.

During implementation of the ART Act, the ACT Government received feedback from stakeholders which indicated that there is a small cohort of people who were allocated gametes either before the first commencement date of the ART Act or during the transitional period, and for whom use of those gametes now does not comply with the ART Act. There are estimated to be 100 to 200 Canberrans who are now legally unable to make use of gametes they previously obtained consistent with the regulatory environment at the time. This group may face difficulties or delays in obtaining alternative gametes due to waiting lists, short supply and high costs. In addition to the financial loss which may be suffered by this cohort, there is a risk that if this cohort of people is unable to use gametes they have already obtained, delays in sourcing alternative gametes may impact their likelihood of conceiving a child.

Transitional provisions are necessary in the introduction of any new legislative scheme to ensure that people operating under previous rules and laws are considered. Transitional provisions are used to set out how to deal with something that has been started prior to an introduction of a law, but not completed before the law commenced.

The proposed amendments enable people who had started their ART journey by having already been allocated gametes before the ART Act had commenced (or during the transitional period of the ART Act) to be able to complete their ART journey in a manner that would have been legally permissible prior to the introduction of the ART regulatory scheme but would now be in breach of the ART Act. The proposed amendments will also enable people who have created embryos or who have already become pregnant prior to the end of the transitional period to be able to complete their family using gametes from the same donor, enabling siblings to be genetically related.

#### Technical amendments to the ART Act

### Amendment to section 40 of the ART Act

The intended policy position for section 40 of the ART Act is: a limit of five families created through ACT-based ART from a single donor; a limit of ten families created through ART in Australia from a single donor; once a family had been created that family could create further siblings; and these limits may be lower if determined by the donor's consent.

However, this policy position is not reflected in the current wording of section 40. As currently drafted, section 40 prohibits the use of a donor's gametes by anyone - including the first four families in the ACT, or the first nine families in Australia, who would otherwise be entitled to have more children via that donor - once there is a fifth family in the ACT or a tenth family in Australia that includes a child born as a result of ART treatment. Clause 4 amends section 40 to correct this unintended drafting error.

## Amendment to section 53 of the ART Act

In the ART Act, section 46 provides that an ART provider must collect certain information about a donor ('mandatory information') before obtaining or using a gamete for ART treatment, and then under section 48 retain that information as a record. Section 53 then sets out a list of information (which mirrors the list of information under section 46) that must be given by the ART provider to the directorgeneral for inclusion in the donor register when the ART provider becomes aware of a live birth resulting from ART treatment. The policy intention is for the ART provider to be obligated to provide the mandatory information (which was collected under section 46) to the director-general within two months after they become aware a child has been born alive as a result of ART treatment.

As currently drafted, there may be scope for section 53 to be read to require ART providers to re-collect all of the mandatory information about donors each time there is a live birth (i.e. require the ART provider to ask the donor for updated information), rather than just providing to the director-general the mandatory information under section 46 (which the ART provider collected when obtaining the gamete).

Clause 5 amends section 53 of the ART Act to clarify that the information required to be given to the director-general refers to the information already collected under section 46(1) and then kept as a record under section 48. The purpose of the proposed amendment is to provide additional clarity to ART providers that the obligation to provide this information to the director-general under section 53 does not include an additional obligation to recollect the information.

## Amendment to section 121 of the ART Act

An amendment to section 121 will introduce a sectional definition to the term 'public official' to ensure the operability of the provision. Clause 6 corrects this minor oversight.

### **CONSULTATION ON THE PROPOSED APPROACH**

# Consultation during development of the ART Act

The ACT Health Directorate (**ACTHD**) conducted targeted consultations with key stakeholders during the development of the ART Act, including meetings with key stakeholders, the dissemination of a discussion paper with opportunities for feedback, analysis of similar existing legislation in other Australian jurisdictions, and discussions with government counterparts in other jurisdictions about the development of their legislation and processes, and lessons learned. Stakeholders included:

#### External stakeholders

- Donor Conceived Australia
- Women's Health Matters
- IVF Australia
- Compass Fertility
- Genea
- Fertility Society of Australia and New Zealand (FSANZ)
- Meridian
- A Gender Agenda
- Health Care Consumers' Association ACT
- Professor Sonia Allan OAM, University of New England

- State-based Government Agencies
- The Victorian Assisted Reproductive Treatment Authority (VARTA)
- NSW Ministry of Health
- SA Health
- the WA Department of Health ART Legislative Review Clinical Excellence Division
- QLD Department of Health

## ACT Government Agencies

- The Human Rights Commission
- Justice and Community Safety
- Canberra Health Services
- Chief Minister, Treasury and Economic Development
- Office of LGBTIQ+ Affairs,
- Access Canberra Registrar of Births, Deaths and Marriages
- Community Services Directorate (CSD) Office for Women

### Consultation on proposed amendments to the ART Act

After the introduction of the ART Act, additional feedback was received from stakeholders and that has informed the Bill.

#### External Stakeholders

As part of the implementation stage of the ART Act, ACTHD consulted with ART providers and received feedback about the application of the ART Act's transitional arrangements and potential impacts on clinical practice. Additionally, ART providers raised concerns about clients who had allocated gametes in storage but who had not yet commenced ART treatments and, under the Act, could no longer use these gametes. Meetings were held with the ACT's ART providers consulting them on the proposed amendments and seeking views on whether they anticipated any unintended consequences arising from the proposed extended transition arrangements.

ACTHD also received community feedback on the legislation, in particular from the LGBTIQA+ community. Concerns were raised about continuing access to gametes that had already been acquired or allocated, and about effects on the supply of donor

gametes. As part of preparation of this Bill, community members who had contacted ACTHD were advised of the proposed amendments and given the opportunity to provide comments on the changes.

ACTHD also met with members of Donor Conceived Australia (DCA) to seek views on the proposed extended transition arrangements. Members at that meeting indicated that they supported extending transition provisions to include the small cohort that found themselves unable to use gametes they had already acquired.

## ACT Government Agencies

The Office of LGBTIQA+ Affairs, the ACT Human Rights Commission and the Justice and Community Safety Directorate (JACS) were consulted on the proposed amendments.

### **CLIMATE IMPACT**

There are no climate impacts anticipated under the Bill.

#### **CONSISTENCY WITH HUMAN RIGHTS**

During the development of the Bill, due consideration was given to its compatibility with human rights as set out in the *Human Rights Act 2004* (ACT) (**Human Rights Act**). As a human rights jurisdiction, the protection of human rights is at the forefront of decision-making in the ACT.

An assessment of the Bill against section 28 of the Human Rights Act is provided below. Section 28 provides that human rights are subject only to reasonable limits set by laws that can be demonstrably justified in a free and democratic society.

## Rights engaged

The ART Act in its entirety interacts with human rights in a number of ways, notably in balancing the right to privacy for donors and the right to the protection of the family and child for donor conceived people. However, the amendments under this Bill are not anticipated to change the overall human rights impact of the ART Act.

The Bill engages the following rights under the Human Rights Act:

- Section 8 Right to equality and non-discrimination (promoted)
- Section 9 Right to life (limited)
- Section 11 Protection of the family and child (promoted and limited)

# Amendments to Part 12 (Transitional) of the ART Act

The proposed amendments to the transitional provisions will engage human rights for those individuals that are directly affected by the transitional arrangements, and their donor-conceived children. The amendments to Part 12 of the ART Act (clauses 7 to 8) engage the right to equality and non-discrimination (*promoted*), right to life (*limited*), and right to the protection of the family and child (*promoted and limited*).

## **Rights Promoted**

This Bill promotes the following rights under the Human Rights Act:

- Section 8 Right to equality and non-discrimination
- Section 11 Protection of the family and child

## Section 8 - Right to equality and non-discrimination

Section 8 of the Human Rights Act provides that everyone is entitled to enjoy their rights without discrimination of any kind and that everyone is equal before the law and entitled to the equal protection of the law without discrimination. The proposed amendments to the transitional provisions of the ART Act will promote the right to equality and non-discrimination as it will seek to address an effect of Part 12 of the ART Act that more negatively impacts the LGBTIQA+ community and single women than other sectors of the community.

New section 132B allows the use of gametes allocated before 28 September 2024 and exempts that use from either the basic or extended provisions. If a person becomes pregnant with such gametes, new section 132C allows the further use of gametes from the same donor. Without new sections 132B and 132C, people who were already allocated gametes, but who have not yet commenced ART treatment or achieved pregnancy are likely to suffer significant financial loss in relation to the expenses arising from re-acquiring gametes. They may also experience delays in ART treatment, which in turn may affect their likelihood of being able to conceive a child.

This group of people were either allocated donated gametes prior to the commencement of the ART Act or during the transitional period. Many individuals in this cohort were unaware at the time they were allocated gametes, that the use of those gametes would become prohibited with the commencement of the ART Act. There are estimated to be between 100 and 200 Canberrans, a high proportion of whom are from the LGBTIQA+ community or are single women, who are now legally unable to make use of the gametes they were previously allocated. Without this Bill, this group will be required to restart their ART journeys and source alternative gametes where they may face delays due to waiting lists, short supply and high costs.

The right to equality and non-discrimination is similarly promoted by the amendments made by clause 8 to section 131, 132 and new sections 132A and 132C. Amended sections 131 and 132 enable people who have already created embryos or become pregnant prior to 28 September 2024 (whether or not the gametes complied with the ART Act at the time they were used), to receive further ART treatment which is exempt from the extended provisions.

New Sections 132A and 132C will allow people who become pregnant with embryos created or gametes allocated before 28 September 2024, to subsequently use gametes from the same donor to complete their families. Without these amendments, the ART Act could result in people who have already started their families being unable to complete their families. These people could be required to discard embryos already created, or source alternative gametes for their subsequent pregnancies where they may face delays due to waiting lists, short supply and high costs, which could impact their likelihood of conceiving a child. Additionally, the ACT Government has received feedback from ART providers that because many of the gametes used for ART treatment in the Territory are sourced from international donors, making contact with these donors to ask for additional information or updated consents (to enable use of their gametes to comply with the ART Act) could be very difficult. Individuals would instead be required to source gametes from different donors.

Each of the limitations on the use of gametes set out above has a more significant impact upon the LGBTIQA+ community than other sectors of the community, given the necessary role of ART treatment in conceiving children for a significant portion of this community. Single women may also be disproportionately impacted. The Bill promotes the right to equality and non-discrimination by addressing this disproportionate impact.

## Section 11 - Protection of the family and child

Section 11 of the Human Rights Act provides that the family is the natural and basic group unit of society and is entitled to be protected by society. The Bill promotes the right to protection of the family, by allowing individuals to complete their families and enabling siblings to be genetically related.

Subsequent pregnancies for a person who became pregnant using already allocated gametes

New section 132C promotes the right to protection of the family as it enables a person who became pregnant using already allocated gametes to then use gametes from the same donor for subsequent pregnancies. Without new section 132C, people who became pregnant with already allocated gametes under new section 132B would not be able to complete their families with genetically related siblings.

# Person who became pregnant before 28 September 2024 or who creates embryos before 28 September 2024

Similarly, the clause 8 amendments to section 131 and 132 also promote the right to protection of the family. This is because it ensures that if a person became pregnant or created embryos before the end of the transitional period, even if that person received ART treatment or created embryos using gametes that no longer complied with the ART Act at the time, the person or their domestic partner would be able to complete their family using gametes from the same donor (for section 131) or use those created embryos (for section 132).

These proposed amendments address a known issue that during the transitional period, some ART providers may have continued providing ART treatment for a period with gametes which no longer complied with the ART Act. Where a person did become pregnant or create embryos in such circumstances, clause 8 will allow them to complete their families or use those embryos.

# Subsequent pregnancies for a person who became pregnant using embryos created before 28 September 2024

As above, new section 132A ensures that if a person became pregnant using embryos created before 28 September 2024, the person or their domestic partner would be able to complete their family using gametes from the same donor, thereby promoting the right to protection of the family. Without new section 132A, people who became pregnant with embryos created prior to 28 September 2024 under section 132 would not be able to complete their families with genetically related siblings.

## **Rights Limited**

This Bill limits the following rights under the Human Rights Act:

- Section 9 Right to life
- Section 11 Protection of the family and child

## 1. Nature of the right and the limitation (s28(a) and (c))

## Section 9 – Right to life

Section 9(1) of the Human Rights Act recognises that everyone has the right to life and that no-one may be arbitrarily deprived of life. The right to life requires the ACT Government to safeguard life where there may be a real and immediate direct or indirect risk to life. The ART regulatory framework promotes the right to life by generally increasing the attainable standard of health of children born from ART procedures.

Therefore, the right to life may be limited for a donor conceived person born from gametes used by an individual covered under the transitional provisions (this includes the existing transitional provisions in Part 12 of the ART Act and the proposed amendments to the transitional provisions as introduced by this Bill). This is because the ART Act contains a number of limitations on the use of gametes which are designed to protect the health, safety and wellbeing of donor conceived people born from those gametes, and consequentially promote their right to life.

Unknowingly forming a consanguineous relationship could lead to the risk of the birth of children with genetic or chromosomal abnormalities, which can cause a threat to life. The ART Act addresses this risk through provisions for access to information via the donor register (Part 5 of the ART Act), and a provision limiting the maximum number of families created through a donated gamete (section 40 of the ART Act). The Bill will mean that an additional estimated 100 to 200 individuals will now be covered by the transitional provisions of the ART Act. For the donor conceived children of these individuals, some of the protections as conferred by the ART Act which promote a donor conceived person's right to life, such as the limitation on the number of families at section 40, will not apply.

## Use of already allocated gametes

New section 132B limits the right to life of the donor conceived children born from the use of the already allocated gametes. The use of the already allocated gametes will be exempted from certain provisions of the ART Act which serve to promote a donor conceived person's right to life. Depending on the time within which gametes were allocated, use of the gametes may be exempted from time limits on use (section 39 of the ART Act), limitations on family (section 40 of the ART Act) and obligations to collect and keep specific information from the donor, and provide that information to the donor register (sections 46, 47, 48 and 53 of the ART Act).

These existing provisions of the ART Act promote the right to life of a donor conceived person by safeguarding the health and wellbeing of donor conceived people. In particular, limits on the number of families that can be created from one donor's gametes (section 40 of the Art Act) promote the right to life of a donor conceived person as it reduces the chances of that donor conceived person unknowingly engaging in an consanguineous relationship. The information collected and required to be provided to the donor register (sections 46, 47, 48 and 53), will include information relevant to maximising the health and wellbeing of the donor conceived person (such as relevant medical information, and knowledge of a person's siblings), which in turn promotes their right to life.

<u>Use for a person who becomes pregnant before 28 September 2024 or who creates</u> <u>embryos before 28 September 2024</u>

Amended section 131 will exempt from the extended provisions the use of further gametes of a donor for ART treatment where a person becomes pregnant prior to 28 September 2024. Amended section 132 will adopt a similar approach for embryos created prior to 28 September 2024 and will apply the extended provisions to the use of those embryos. This approach varies from the current transitional arrangements, as under the current arrangements, people who became pregnant, or who created embryos, within the transitional period (i.e. between 29 March 2024 and 27 September 2024) are only exempt from the basic provisions. The new provisions will also allow this group to be exempt from the extended provisions. These provisions limit the right to life, to the extent that it will allow more donor conceived children to be born who will not take the benefit of the legislated requirements to obtain and store certain information (sections 46, 47, and 48). This could result in donor conceived people being unable to access that information from ART providers.

Use for subsequent pregnancies for a person who becomes pregnant with already allocated gametes + for a person who becomes pregnant using embryos created before 28 September 2024

As above, allowing the subsequent use of a donor's gametes after a person becomes pregnant using already allocated gametes limits the right to life of the donor conceived children born from that use. The subsequent use of the donor's gametes will also be exempted from provisions of the ART Act which serve to promote a donor conceived person's right to life, in the same (or similar) way to the initial use. The subsequent use of a donor's gametes will also be exempted from provisions of the ART Act if a person becomes pregnant using embryos created before 28 September 2024.

## Section 11 - Protection of the family and child

Section 11 of the Human Rights Act provides that the family is the natural and basic group unit of society and is entitled to be protected by society. Section 11(2) of the Human Rights Act provides that every child has the right to the protection needed by the child because of being a child, without distinction or discrimination of any kind.

The Bill will interact with the rights of a specific group of donor conceived children born from gametes used by individuals covered under the transitional provisions of the ART Act, as the Bill may limit their right to know their genetic identity. Provisions under the ART Act such as access to information via the donor register (Part 5 of the ART Act), and requirements to collect and keep certain information before obtaining or using a gamete (sections 46-48 of the ART Act) promotes the best interests of the child by ensuring greater record-keeping and accessibility of heritage information for donor conceived people. The right to the protection of the family and child is engaged as the Bill allows the use (and subsequent use) of gametes which do not comply with these

provisions in limited circumstances (where those gametes were already allocated prior to the commencement of the ART Act or during the transitional period). For the donor conceived children of the additional cohort of individuals covered by the transitional provisions, some of the protections as conferred by the ART Act which promote a donor conceived person's right to protection of the family and child will not apply.

## Use of already allocated gametes

New section 132B limits the right to protection of the family and child in the same way as it limits the right to life for donor conceived children born from the use of the already allocated gametes. The use of the already allocated gametes will be exempted from certain provisions of the ART Act which were designed to safeguard a donor conceived person's right to protection of the family and child. Depending on the time within which gametes were allocated, use of the gametes may be exempted from time limits on use (section 39 of the ART Act), limitations on family (section 40 of the ART Act) and obligations to collect and keep specific information about the donor, and provide that information to the donor register (sections 46, 47, 48 and 53 of the ART Act).

In particular, obligations to obtain, keep and provide specific information about the donor (sections 46, 47, 48 and 53 of the ART Act), are intended to promote the right of a donor conceived child's right to know their genetic identity. These provisions protect the right for a child to know their identity in accordance with Article 8 of the United Nations Convention on the Rights of the Child:

#### Article 8

- 1. States Parties undertake to respect the right of the child to preserve his or her identity, including nationality, name and family relations as recognized by law without unlawful interference.
- 2. Where a child is illegally deprived of some or all of the elements of his or her identity, States Parties shall provide appropriate assistance and protection, with a view to re-establishing speedily his or her identity.

A lack of information around heritage can cause significant distress among donor-conceived people, and within families. The rights of the child are interpreted by reference to the rights contained in the Convention on the Rights of the Child, which requires that the best interests of the child must be a primary consideration in any decision that affects the child. 'Best interest' encompasses requirements of health, education, cultural and kinship relations, and opportunities for social and personal development.

Also, the rights of donor conceived children born from the use of gametes under the transitional arrangements will be limited because they will not be protected by the limits on families (section 40 of the ART Act). Section 40 safeguards the rights of family and children by seeking to reduce the risk of unknowing consanguineous relationships,

which in turn promotes the long-term wellbeing of donor conceived people and their families.

<u>Use for a person who becomes pregnant before 28 September 2024 or who creates</u> <u>embryos before 28 September 2024</u>

The exemption from the above list of provisions of the ART Act for use of a gamete or embryo under clause 8 – amendments to sections 131 and 132 – limits the rights of the donor conceived child to protection of the family and child in the same way as above.

Subsequent pregnancies for a person who became pregnant using already allocated gametes + for a person who becomes pregnant using embryos created before 28 September 2024

The exemption from the above list of provisions of the ART Act for subsequent use under clause 8 – new section 132A and new section 132C – limits the rights of the donor conceived child to protection of the family and child in the same way as above.

## 2. Legitimate purpose (s28(b))

The objective sought to be achieved by the Bill is to ensure that individuals who have already started their ART journey prior to the commencement of the ART Act (including prior to the end of the transitional period) – whether through being already allocated gametes, already created embryos or having become pregnant – are largely able to complete their ART journey in a way they would have been able to before the Territory's new regulatory scheme for ART was introduced (with only a small number of regulatory provisions of the ART Act continuing to apply); promoting the right to protection of the family and child. In order to ensure that an individual who commenced their ART journey before or during the transitional period can use already allocated gametes or complete their families, it is necessary to exempt the use of those gametes from some of the ART Act's protections.

Expanding the scope of the transitional provisions of the ART Act limits the rights of donor conceived people born from the use of gametes that are exempt from certain provisions of the ART Act during the relevant transitional period. However, this measure is necessary to prevent delays to ART treatment for a person who has already started their ART journey, which may impact that person's likelihood of conceiving a child. For example, aside from the significant additional costs, there can be difficulties for a person seeking to obtain alternative gametes due to waiting lists and short supply. There is a scarcity of Australian donors, resulting in the need to source gametes from overseas gamete banks; and the contracts these banks have with their donors may not comply with ACT legislation. Additionally, age-related decline in fertility may affect some women's chances of achieving pregnancy if delays

are prolonged. Many clients of ART treatment have experienced or are experiencing infertility, and delays could risk an individual's chance to conceive.

The ACT Government received feedback from stakeholders — including correspondence from both ART providers and constituents — which indicated that this was a pressing and substantial concern for this cohort. The ACT Government received estimates from the Territory's ART providers that this issue affected between 100 and 200 Canberrans. Stakeholder concerns mostly related to concerns about compliance with the ART Act, as well as financial and availability barriers to accessing replacement gametes. This issue has had a more significant impact on the LGBTIQA+ community, due to the necessary role of ART treatment in conceiving children for a significant portion of this community. As a result, the amendments support the right to equality and non-discrimination by addressing this disproportionate impact. The Bill's amendments to the transitional arrangements serve a legitimate purpose to enable individuals to complete their ART journey and prevent delays which could affect an individual's chance to conceive.

# 3. Rational connection between the limitation and the purpose (s28(d))

When a new legislative scheme is established, transitional provisions are a way to preserve existing rights prior and provide certainty and clarity about when and how the new scheme is intended to operate.

This Bill amends the current transitional provisions of the ART Act by applying the existing staged approach in the current transitional arrangements under the ART Act to an additional small group of individuals and couples. The staged approach gradually applies more of the ART Act's regulatory provisions over time, striking a more nuanced balance between the rights of individuals who have already started their ART journey (including distinguishing between allocation of gametes, creation of embryos and becoming pregnant) and the rights of donor conceived people.

The Bill creates two lists of exempted provisions.

The basic provisions are as follows:

- section 39 (Donated gametes or embryos time limits on use);
- section 40 (Donated gametes or embryos limits on number of families); and
- section 53 (Mandatory information).

The extended provisions are as follows:

- all the basic provisions listed above;
- section 46 (Requirement to collect information about gamete provider);

- section 47 (Requirement to collect information about person undergoing ART treatment); and
- section 48 (Requirement to keep records).

The rationale for dividing the exempted provisions in this manner relates to the commencement of each of the provisions. The provisions listed under the basic provisions either commenced on 28 September 2024 or will commence on 28 March 2025. The three additional provisions listed under the extended provisions all commenced on 29 March 2024. The purpose for setting out two sets of exempted provisions is to ensure that in the course of enabling individuals to complete their families, the rights of a donor conceived person born from the relevant ART treatment is not disproportionately impacted. For instance, if a gamete was allocated between 29 March and 28 September 2024, the ART provider ought to have known about the provisions which commenced on 29 March 2024, and so only the basic provisions should be exempted.

Relevant Stage of ART and Period	Exempted Provisions of ART Act
Embryo created prior to 28 September 2024 (and any subsequent gamete or embryo created from a subsequent gamete)	Extended provisions
First gamete allocated prior to 29 March 2024 (and any subsequent gamete or embryo created from a subsequent gamete)	Extended provisions
First gamete allocated between 29 March and 28 September 2024 (and any subsequent gamete or embryo created from a subsequent gamete)	Basic provisions
Pregnant prior to 28 September 2024 (and any subsequent gamete or embryo created from subsequent gamete)	Extended provisions

The amendments to the transitional provisions of the ART Act will, in the ways outlined above, achieve the objective of ensuring that individuals and couples who have already started their ART journey are able to complete their ART journey.

## Use of already allocated gametes

New section 132B exempts the use of gametes allocated before 29 March 2024 (the commencement date of the ART Act) from the extended provisions. New section 132B also exempts the use of gametes allocated between 29 March 2024 and 28 September 2024 (the transitional period of the ART Act) from the basic provisions.

For individuals who have already undergone the process of obtaining or being allocated gametes – at the time when those gametes were allocated to them, those individuals may not have been aware (or were unclear) that use of those gametes would no longer comply with the ART Act. Although ART providers in the ACT were advised of the upcoming legislation, and targeted stakeholder consultation occurred during the development of the legislation, individuals seeking to undertake or undertaking ART treatment were not individually consulted and may not have received accurate guidance from their ART provider. There were no legislative requirements which regulated the use of gametes in the Territory prior to the introduction of the ART Act, and ART providers operating in the ACT have indicated that they did not understand the full scope of their obligations under the ART Act until after the transitional period had commenced.

Exempting the use of those already allocated gametes from the extended or basic provisions relating to a child's right to know their genetic identity (limiting the rights to protection of the family and child) and limits on families to protect against unknowing consanguineous relationships (limiting the right to life), therefore will allow those gametes to be used in a way that does not breach the ART Act. This is directly connected to the purpose of the Bill as new section 132B will enable individuals who have started their ART journey by having already been allocated gametes to use those gametes and continue their ART journey, in turn supporting the right to protection of the family and child, and the right to equality and non-discrimination acknowledging stakeholder feedback about the disproportionate impact on members of the LGBTIQA+ community. New section 132B will also prevent the need for this cohort of people to source new gametes which could lead to delays in a person's access to ART treatment. Because many clients of ART treatment have experienced or are experiencing infertility, there is a time sensitive element to providing ART treatment and delays could risk an individual's chance to conceive.

# Subsequent pregnancies for a person who became pregnant using already allocated gametes

New section 132C means that those who were allocated gametes prior or during the transitional period can complete their family. New section 132C exempts the subsequent use of a donor's gametes from either the basic or extended provisions (and protections relating to the right to protection of the family and child and the right to life) if an individual becomes pregnant with the gametes allocated prior or during the transitional period. The provisions exempted will depend on when the gametes used

for the initial pregnancy were allocated. This is directly connected to the purpose of the Bill as new section 132C will enable individuals who have started their ART journey by having already been allocated gametes to use gametes from the same donor to have subsequent families and complete their ART journey, again supporting the right to protection of the family and child.

Without this amendment, even if a person could use the already allocated gametes under new section 132B they would not be permitted to use any newly sourced gametes from the same donor to complete their family unless those gametes complied with the ART Act. The ACT Government has received feedback that because most donor gametes used by the Territory's ART clients are from international donors, ensuring that these donors' gametes comply with the ART Act can be very difficult. New section 132C will therefore prevent the need for this cohort of people to source alternative gametes (which may result in siblings being genetically unrelated or at least not full siblings) and allow them to complete their families.

# Subsequent pregnancies for a person who became pregnant before 28 September 2024

Clause 8 amendments to section 131 exempts the subsequent use of a donor's gametes from certain provisions of the ART Act (and protections relating to the right to protection of the family and child and the right to life) if a person has already become pregnant using that same donor's gametes before 28 September 2024. This will achieve the purpose of the Bill as it addresses a known issue that during the transitional period some ART providers may have continued providing ART treatment for a period of time with gametes that no longer complied with the ART Act. Where a person did become pregnant in such circumstances, clause 8 will allow that person to subsequently use the same donor's gametes. This enables the person to complete their families with siblings who are genetically related and have the same protections under the ART Act as one another, supporting the right to the family and child.

# <u>Use of embryos created before 28 September 2024 and subsequent pregnancies for a person who became pregnant using embryos created before 28 September 2024</u>

Clause 8 also amends section 132 so that the use of embryos created before the end of the transitional period is exempt from the extended provisions. This will achieve the purpose of the Bill as it addresses a potential issue that during the transitional period, some ART providers may have created embryos for a period of time with gametes that no longer complied with the ART Act. The creation of an embryo represents a later stage of the ART process than the allocation of gametes, and because an embryo is created from multiple persons' genetic material, a barrier to using that embryo would impact each of the rights to family and right to equality and non-discrimination of all the individuals whose genetic material forms part of the embryo.

The amendment to section 132 under clause 8 will also prevent the need for people who have already created embryos to source new gametes (either sperm or oocyte or both), to create new embryos - which could lead to delays in a person's access to ART treatment. Because many clients of ART treatment have experienced or are experiencing infertility, there is a time sensitive element to providing ART treatment and delays could risk an individual's chance to conceive. Further, for a person who is relying on collection of their own oocytes to create an embryo, the number of oocytes available to them will be limited by the person's fertility, age and the success of procedures to collect those oocytes. Therefore, for some people, an inability to utilise embryos created using donated sperm and their own oocytes, may cause not only delay, but where further oocytes are not available, pose a barrier to conceiving a child.

Where a person becomes pregnant using such an embryo, new section 132A will also allow that person to subsequently use the same donor's gametes. This enables the person to complete their family and ART journey and ensures that siblings are genetically related and have the same protections under the ART Act as one another, supporting the right to the family and child.

# 4. Proportionality (s28 (e))

Any limitation on human rights caused by the amendments to the transitional provisions of the ART Act have been carefully targeted and safeguarded and alternative approaches were considered in the course of drafting these amendments. The reasoning as to why each measure represents the least restrictive means reasonably available to achieve the objective of allowing individuals to complete their ART journeys is detailed below.

#### Use of already allocated gametes

## Alternative options

The two alternative approaches considered against amending the transitional provisions to allow use of already allocated gametes included:

- a compensation approach, and
- a no legislative amendment approach.

The compensation approach would involve compensating individuals who have already been allocated gametes which now do not comply with the ART Act on the basis that these gametes can no longer be used. This option would mean that new gametes must be sourced which comply with all the requirements under the ART Act.

Although this option would address the financial loss experienced by this cohort in relation to the expenses arising from acquiring gametes, it fails to address the risk of

delay caused by the need to source new gametes to this cohort of people. For example, aside from the significant additional costs, there can be difficulties for a person seeking to obtain alternative gametes due to waiting lists and short supply. Barriers include a scarcity of Australian donors, resulting in the need to source gametes from overseas gamete banks; and that the contracts these banks have with their donors may not comply with ACT legislation. Many clients of ART treatment have experienced or are experiencing infertility and so there is often a time sensitive element to providing ART treatment. Delays arising from the need to source new gametes could affect an individual's chance to conceive.

A no legislative amendment approach would result in both financial loss and delay. No legislative amendments would mean that individuals would be unable to use the gametes that have already been allocated to them, unless they had already become pregnant prior to 28 September 2024. However, there is a known cohort of people (estimated for between 100 and 200 Canberrans) who either did not or were unable to become pregnant prior to this date. For this cohort of people, the option of no legislative amendment leaves no recourse apart from restarting their ART journeys by sourcing new gametes. However, as above, sourcing new gametes would result in not only financial loss, but present a risk to an individual's chance to conceive.

The two other Australian jurisdictions with comparable transitional provisions in their ART legislation are Queensland and New South Wales (NSW). However, the key difference between the Territory's ART Act and Queensland and NSW is the length of lead time into commencement. For instance, NSW's legislation passed in 2007 and only commenced three years later, in 2010. Donor conceived people born during this time would not have been covered by the legislation.

The Territory's staged commencement means that donor conceived people will have some protections which promote their human rights under the ART Act upon and shortly after commencement. The approach of having a shorter commencement period paired with transitional provisions scoped to a necessary degree (to balance the rights of people seeking ART treatment with the rights of donor conceived children) ensures that a level of legislative protection is still conferred for donor conceived people born or conceived in the interim period where legislation has not fully commenced and represents a preferable approach from a human rights perspective.

## Safeguards

There are a number of safeguards for new section 132B to ensure that the measure is carefully targeted so as to minimise its limitation of the right to life and the right to protection of the family and child. The provision only captures people who were allocated gametes prior to a certain date. This means that the individuals affected by this clause and their donor-conceived children are a closed cohort – i.e. once all the individuals who were allocated gametes prior to 28 September 2024 have completed their ART journeys, new section 132B will not have continued application.

A key safeguard is the staged approach of the clause. This staged approach ensures that the provisions of the ART Act are only exempt so far as necessary to enable the use of already allocated gametes.

In effect, new section 132B allows the use of the already allocated gametes in the same way as use of the gametes would have been allowed at the time of allocation. So, if the gametes were allocated before the commencement of the ART Act, the extended provisions apply to its use as compared to the basic provisions which apply to gametes allocated during the transitional period. The main point of difference between the two lists is that gametes allocated during the transitional period will still be required to comply with requirements in relation to collecting and keeping information (see sections 46 to 48) that commenced in March 2024. New section 132B ensures that for gametes allocated during the transitional period, these information collection obligations will also apply (as these obligations applied at the time the gametes were allocated).

The staged approach is contrasted to a 'blanket' approach which would mean that the same list of provisions applied to the use of all gametes allocated before 28 September 2024. One purpose of staging the commencement of the ART Act was to maximise the information which is available to donor conceived persons born prior to the commencement of the donor register and ensure those records are retained. If even gametes which were allocated after the commencement of the ART Act do not need to satisfy the information collection requirement (which is the effect of the 'blanket' option), the purpose of staging the ART Act's commencement is not met.

New section 132B's staged approach more carefully targets the amendment so as to limit the human rights impact for donor conceived children born from gametes allocated during the transitional period (29 March 2024 to 27 September 2024). These donor conceived children will have a greater guarantee that the ART providers have kept certain records in accordance with sections 46 to 48 (which promotes the rights of the child to know their genetic identity).

Another safeguard relates to the careful targeting of when a gamete is 'allocated'. This ensures that the cohort of people that new section 132B will apply to is strictly defined. For instance, gametes sourced directly by ART providers which have not been allocated to a specific client are not included. This prevents new section 132B from applying to the use of gametes acquired on bulk by an ART provider, which safeguards the number of individuals this amendment will apply to, and their donor conceived children.

Other protections will still apply to donor conceived children

The measures under new section 132B will mean that donor conceived children born from the use of these allocated gametes will not have certain protections under the ART Act. The basic provisions that will not apply for all donor conceived children born from gametes permitted for use under new section 132B are:

- Time limits on the use of a gamete (section 39).
- Limits on the number of families that can be created from one donor's gametes (section 40).
- Requirement to provide certain information for inclusion in the donor register (section 53).

However, other provisions of the ART Act must still be observed before use of these gametes are compliant with the ART Act. For example, the general registration requirements for ART providers (see Division 4.1), prohibiting the use of gametes for research (see section 35) and prohibiting the posthumous use of gametes (see section 36). These provisions are not exempted when using already allocated gametes, and promotes a donor conceived child's right to life and right to protection of the family. New section 132B does not result in donor conceived children born from the use of already allocated gametes having no protections under the ART Act, and only the minimum necessary provisions are exempted to ensure that the objective of the Bill is achieved.

For donor conceived children born from the use of gametes which were allocated before 29 March 2024, the following additional provisions of the ART Act in relation to collecting and keeping certain information will not apply (see 'extended provisions' under clause 7).

- Requirement to collect information about a donor before obtaining a gamete or before using a gamete (section 46).
- Requirement to collect information about a person undergoing AR T treatment before using a gamete (section 47).
- Requirement to keep certain records in relation to each gamete or embryo an ART provider has in its possession (section 48).

However, the exemptions to sections 46 to 48 of the ART Act do not mean that no information is being collected by ART providers. ART providers are required to maintain accreditation with the Fertility Society in order to be a registered ART provider under the ART Act (section 12 of the ART Act). To maintain accreditation the Fertility Society requires ART providers to comply with the NHMRC Guidelines. Therefore, although the NHMRC Guidelines are not directly legally binding on ART providers, failure to comply with those guidelines would put the ART provider's accreditation at risk. The NHMRC Guidelines include requirements about information collection and sharing. Notably the NHMRC Guidelines provide that:

 ART providers must not use donated gametes in ART treatment unless the donor has consented to the release of their identifying information to the donor conceived person (see paragraphs 4.6.1 and 5.5.1).

- ART providers that are approached by a donor conceived person born from gametes donated at that clinic, who has reached the age of 18, or has been assessed as sufficiently mature, must provide the following information, as a minimum (see paragraphs 5.9.1 and 5.9.2):
  - medical history, family history and any existing genetic test results that are relevant to the future health of the person who would be born (or any subsequent offspring of that person) or the recipient of the donation;
  - details of the physical characteristics of the gamete donor;
  - the number, age and sex of persons already born from the gametes provided by the same gamete donor and the number of families involved;
  - o any identifying information about the gamete donor; and
  - any identifying information that another donor conceived person born from the gametes of the same donor has consented to being released.
- ART providers should have procedures for record keeping that include the
  collection, recording and reporting of data about persons, treatments, procedures
  and results. ART providers must also have provisions to keep records indefinitely
  (or at least for the expected lifetime of any persons born) (see paragraphs 5.9.3).

Given that ART providers in the Territory must comply with the above guidelines in order to maintain their accreditation (which is mandated by section 12 of the ART Act), new section 132B's exemptions to sections 46 to 48 of the ART Act would only limit a donor conceived child's right to life and right to know their genetic heritage to the extent that these obligations are not explicitly legislatively required.

In order to maintain their accreditation as an ART provider which is necessary for registration under section 12 of the ART Act, ART providers are obligated to collect information relevant to promoting a donor conceived person's right to life: such as medical history, and the age, sex and number of half siblings. Similarly, ART providers are still obligated to collect information that would promote a donor conceived person's right to know their genetic identity: such as family history and details of the physical characteristics of the gamete donor.

In terms of accessing information, donor conceived children born from the use of gametes under new section 132B will not be able to access their information via the donor register under Part 5 of the ART Act. This does represent a barrier on a donor conceived person's right to know their genetic heritage. However, this is the case for all donor conceived children born from ART treatment which was provided prior to the commencement of Part 5 of the ART Act – which is scheduled to commence on 28 March 2025. For these donor conceived children, in addition to the NHMRC Guideline requirements outlined above, Division 6.3 of the ART Act also provides an alternate legislative access pathway. These alternative pathways to obtaining

information serve as guardrails to narrow the effect that a delayed commencement or exemption to Part 5 of the ART Act may have on the rights of a donor conceived child to know their genetic identity.

Donor conceived people who cannot access information via the donor register may obtain 'accessible information' about their donor directly from the ART provider (via section 76 of the ART Act). The accessible information which may be accessed directly from the ART provider includes:

- The donor's ethnicity and physical characteristics.
- The donor's relevant medical history.
- The sex and year of birth of each person born as a result of ART treatment using a donated gamete of the donor.
- Any other information about the donor (including identifying information) if the donor has consented to its disclosure, and subject to any restrictions on disclosure stated by the donor.

New section 132B also exempts the use of already allocated gametes from the legislative limits on the number of families that can be created from one donor's gametes (see section 40 of the ART Act). This measure limits a donor conceived person's right to life as the purpose of section 40 of the ART Act is to decrease the risk of a donor conceived person from unknowingly entering into a consanguineous relationship. However, as above, the NHMRC Guidelines serve as safeguards to this limitation. The NHMRC Guidelines provide that:

- ART providers must take all reasonable steps to minimise the number of families created through donated gamete treatment programs (see paragraph 5.3.1).
- Gametes from a single donor must be used to create only a limited number of families. Paragraph 5.3.2 of the NHMRC Guidelines further outlines a list of factors that ART providers must consider in their decision making.

The limiting effect on a donor conceived person's right to life as a result of the exemption to section 40 of the ART Act is therefore minimised given the above guidelines. Even without section 40 applying, ART providers must adhere to reasonable family limits. Following the commencement of the ART Act, ART providers in the Territory must comply with the above guidelines in order to maintain their accreditation. This is legislatively mandated by section 12 of the ART Act, which requires that a provider hold ART accreditation in order to be eligible to be registered as an ART provider in the Territory.

<u>Subsequent pregnancies for a person who became pregnant using already allocated gametes</u>

# Alternative options

There are no real alternative options that would achieve the policy objective of enabling a person who started their ART journey by acquiring gametes prior to the end of the transitional period to complete their families other than new section 132C, which exempts the subsequent use of a donor's gametes from certain provisions of the ART Act for people who become pregnant with gametes that were allocated before 28 September 2024.

A no legislative amendment approach would mean that individuals seeking to use the gametes that have already been allocated to them under new section 132B, would not be able to use gametes from the same donor for subsequent pregnancies. This is because without new section 132C, the subsequent use of the donor's gametes would not be exempt from the necessary provisions and this in turn would prevent the use of those gametes in a compliant manner. This would result in individuals who have already become pregnant having to source new gametes for their subsequent pregnancies, preventing siblings in one family being genetically related, or at least preventing them being full genetic siblings.

# Safeguards

New section 132C has a number of safeguards to ensure that the measure is carefully targeted so as to minimise its engagement with human rights. As above with the proportionality analysis for new section 132B, new section 132C is also only applicable to a closed cohort. New section 132C only captures people who become pregnant with gametes allocated prior to a certain date. This means that once all the individuals who were allocated gametes prior to 28 September 2024 have completed their ART journeys, new section 132C will not have continued application.

A key safeguard is the staged approach of the clause. New section 132C allows the subsequent use of a donor's gametes in the same way as the gametes already allocated are allowed to be used under new section 132B. So, if the gametes were allocated before the commencement of the ART Act (i.e. before 29 March 2024), the extended provisions apply to both the initial use (to become pregnant) and the subsequent use of gametes from the same donor. The basic provisions will apply to the subsequent use of gametes from the same donor if the initial gametes were allocated during the transitional period.

New Section 132C's staged approach more carefully targets the amendment so as to limit the human rights impact for donor conceived children born from subsequent use. It necessarily mirrors the staged approach in new section 132B to ensure that an individual can complete their family using the same donor's gametes, and to ensure that each child in the family has the same protections under the ART Act.

Other protections will still apply to donor conceived children

The above proportionality analysis for new section 132B applies here given that the staged approach is mirrored. For donor conceived children born from the subsequent use of a donor's gametes under new section 132C, certain protections under the ART Act will not apply. However, as above, this does not mean all provisions of the ART Act are exempt from application. Provisions such as prohibiting the posthumous use of gametes (see section 36) will still apply to the use of gametes for ART treatment under this clause, which promotes a donor conceived child's right to life and right to protection of the family.

As above, ART providers must still meet the requirements under the NHMRC Guidelines in order to maintain their accreditation. The limitations to a donor conceived person's human rights as a result of the staged exemptions therefore only extend so far as those obligations for collecting, keeping and sharing information, as well as family limits are not explicitly legislatively required. Even without certain provisions applying, ART providers must adhere to reasonable practices under the NHRMC Guidelines which were designed to protect the rights of the donor conceived person.

Furthermore, donor conceived children born from the use of gametes under new section 132C will also be able to access the alternate legislative pathway to obtain information (via section 76 of the Act).

<u>Subsequent pregnancies for a person who became pregnant before 28 September</u> 2024

### Alternative options

The primary objective for clause 8 – amendments to section 131 is to address the known risk that some people may have become pregnant using non-compliant gametes during the transitional period (likely through no fault of their own) and to enable those people to complete their family.

The alternative approach considered was to design a specific carveout for these people. It was envisaged that the carveout would apply if someone became pregnant between 29 March 2024 and 28 September 2024 (transitional period), using gametes that did not comply with sections 46 to 48. The carveout would allow that individual's subsequent pregnancies using the same donor's gametes to be subject to the extended provisions. However, there are two key issues with this approach. Firstly, under section 131 of the ART Act, someone who became pregnant between 29 March and 28 September 2024 (with the embedded assumption that those gametes were compliant with the ART Act), would only be subject to the basic provisions for their subsequent pregnancies. It would be difficult to justify why someone who became pregnant with non-compliant gametes was subject to greater exemptions for their subsequent pregnancy than someone who became pregnant with compliant gametes.

Secondly, the carve out essentially results in existing section 131(3)(c) of the ART Act having no work to do. For those people whose subsequent pregnancies would have

been exempt from the basic provisions which mirrors section 131(3)(c), the ART provider would have already collected and kept the necessary information for those gametes (i.e. gametes would already comply with sections 46 to 48 of the ART Act) and so there is no practical difference in whether the subsequent uses are exempt from the extended provisions or the basic provisions. For those people who became pregnant between 29 March and 27 September 2024 where the necessary information for those gametes were not collected (i.e. gametes were used in breach of sections 46 to 48), the policy objective is to address this known issue and for their subsequent pregnancies to be exempt from the extended provisions.

## Safeguards

Clause 8 amends section 131 so that anyone who became pregnant prior to 28 September 2024 can have subsequent pregnancies using the same donor's gametes and be exempt from the extended provisions. As above with the proportionality analysis for previous clauses, clause 8 is also only applicable to a closed cohort – namely people who became pregnant prior to a certain date. This means that once all the individuals who became pregnant prior to 28 September 2024 have completed their ART journeys, clause 8 will not have continued application.

Furthermore, clause 8 is carefully targeted so that the 'grace period' whereby an ART provider or consumer may genuinely have been unaware that the gametes used for ART treatment did not comply (i.e., the ART providers did not have strong awareness at commencement of the ART Act and the details of their obligations under sections 46 to 48) ceases on 28 September 2024. This date was chosen as it ties together with the end of the transitional period of the ART Act. Furthermore, by around July 2024, the ACT Government was in contact with all ART providers and other key stakeholder groups in the form of correspondence, meetings, and information packs to address any uncertainties.

Other protections will still apply to donor conceived children

The rights of donor conceived people born from the subsequent use of a donor's gametes where a person became pregnant prior to 28 September 2024 will be limited to some extent – namely the right to life and right to protection of the family.

The measures under clause 8 will mean that donor conceived children born from the use of gametes permitted under this clause are exempted from the following provisions under the ART Act.

- Time limits on the use of a gamete (section 39).
- Limits on the number of families that can be created from one donor's gametes (section 40).
- Requirement to collect information about a donor before obtaining a gamete or before using a gamete (section 46).

- Requirement to collect information about a person undergoing ART treatment before using a gamete (section 47).
- Requirement to keep certain records in relation to each gamete or embryo an ART provider has in its possession (section 48).
- Requirement to provide certain information for inclusion in the donor register (section 53).

This aligns with the exemptions in new sections 132B and 132C, and so the same proportionality assessment detailed above applies here. To summarise, clause 8 does not result in donor conceived children born from the use of gametes permitted under this clause having no protections under the ART Act, and only the necessary provisions are exempted to ensure that the objectives of the Bill are achieved – i.e. to enable an individual to complete their family.

The NHMRC Guidelines which all accredited ART providers are obligated to comply with to maintain their accreditation sets out requirements which mirror these exempted provisions. Therefore, exemptions to the ART Act introduced by clause 8 would only limit a donor conceived child's right to life and right to know their genetic heritage to the extent that these obligations are not explicitly legislatively required.

An alternative legislative pathway to enable this cohort of donor conceived children to obtain information is provided for under Division 6.3 of the ART Act. This alternative pathway provides guardrails to narrow the effect that a delayed commencement or exemption to Part 5 of the ART Act may have on the rights of a donor conceived child to their genetic identity.

<u>Use of embryos created before 28 September 2024 and subsequent pregnancies for a person who became pregnant using embryos created before 28 September 2024</u>

## Alternative options

The primary objective for new section 132A is to address the known risk that some ART providers may have created embryos using non-compliant gametes during the transitional period.

There are no real alternative options that would achieve the policy objective of enabling a person who started their ART journey by creating embryos prior to the end of the transitional period to use those embryos and then (if they become pregnant) subsequently complete their families other than the amendments to section 132 and new section 132A.

A no legislative amendment approach would mean that some individuals would not be able to use the embryos that have already been created during the transitional period with gametes that no longer complied with the ART Act — which may have occurred through no fault of their own. The creation of an embryo represents a later stage of

the ART process than the allocation of gametes, and because an embryo is created from multiple persons' genetic material, a barrier to using that embryo would impact each of the rights to family and right to equality and non-discrimination of the individuals whose genetic material forms part of the embryo.

Furthermore, where a person becomes pregnant using such an embryo, a no legislative amendment approach would mean that an individual would not be able to use gametes from the same donor for subsequent pregnancies. This is because without new section 132A, the subsequent use of the donor's gametes would not be exempt from the necessary provisions and this in turn would prevent the use of those gametes in a compliant manner. This would result in individuals who have already become pregnant having to source new gametes for their subsequent pregnancies, preventing siblings in one family to be genetically related.

# Safeguards

The amendments to section 132 and introduction of new section 132A under clause 8 has a number of safeguards to ensure that the measure is carefully targeted so as to minimise its engagement with human rights. As above with the proportionality analysis for new section 132B, new section 132A and amendments to section 132 are also only applicable to a closed cohort. These amendments only capture people who had embryos created before 28 September 2024 or who become pregnant with such embryos. This means that once all the individuals who created embryos prior to 28 September 2024 have completed their ART journeys, these amendments will not have continued application.

Furthermore, these amendments are carefully targeted so that the 'grace period' whereby an ART provider or consumer may genuinely have been unaware that the gametes used for ART treatment did not comply (i.e. the ART providers did not have strong awareness at commencement of the ART Act and the details of their obligations under sections 46 to 48) ceases on 28 September 2024. This date was chosen as it ties together with the end of the transitional period of the ART Act. Furthermore, by around July 2024, the ACT Government was in contact with all ART providers and other key stakeholder groups in the form of correspondence, meetings, and information packs to address any uncertainties.

Other protections will still apply to donor conceived children

The rights of donor conceived people born from the use of an embryo created before 28 September 2024 or from the subsequent use of the same donor's gametes will be limited to some extent.

The measures under new section 132A and the amendments to section 132 will mean that donor conceived children born from the use of gametes or embryos permitted under these amendments are exempted from the following provisions under the ART Act.

- Time limits on the use of a gamete (section 39).
- Limits on the number of families that can be created from one donor's gametes (section 40).
- Requirement to collect information about a donor before obtaining a gamete or before using a gamete (section 46).
- Requirement to collect information about a person undergoing ART treatment before using a gamete (section 47).
- Requirement to keep certain records in relation to each gamete or embryo an ART provider has in its possession (section 48).
- Requirement to provide certain information for inclusion in the donor register (section 53).

This aligns with the exemptions in new sections 132B and 132C, and so the same proportionality assessment detailed above applies here. To summarise, these amendments do not result in donor conceived children born from the use of such embryos or gametes having no protections under the ART Act.

The NHMRC Guidelines which all accredited ART providers are obligated to comply with to maintain their accreditation sets out requirements which mirror the exempted provisions. Furthermore, an alternative legislative pathway to enable this cohort of donor conceived children to obtain information is provided for under Division 6.3 of the ART Act. This alternative pathway provides guardrails to narrow the effect that a delayed commencement or exemption to Part 5 of the ART Act may have on the rights of a donor conceived child to their genetic identity.

# ASSISTED REPRODUCTIVE TECHNOLOGY AMENDMENT BILL 2025

Human Rights Act 2004 - Compatibility Statement

In accordance with section 37 of the *Human Rights Act 2004* I have examined the **ASSISTED REPRODUCTIVE TECHNOLOGY AMENDMENT BILL 2025**. In my opinion, having regard to the Bill and the outline of the policy considerations and justification of any limitations on rights outlined in this explanatory statement, the Bill as presented to the Legislative Assembly **is** consistent with the *Human Rights Act 2004*.

Tara Cheyne MLA

Attorney-General

### **CLAUSE NOTES**

### Clause 1 Name of Act

This clause provides that the title of the Act will be the Assisted Reproductive Technology Amendment Act 2025 (the Act).

### Clause 2 Commencement

This clause provides the commencement date of the Act. Clause 5, which amends section 53 of the *Assisted Reproductive Technology Act 2024*, will commence on the later date of the two following dates: the commencement of section 53 of the *Assisted Reproductive Technology Act 2024*, anticipated for 28 March 2025; or the day after this Act's notification day.

All other provisions under the Act commence on the day after this Act's notification day.

# Clause 3 Legislation amended

This is a formal clause identifying that the Act amends the Assisted Reproductive Technology Act 2024.

# Clause 4 Donated gametes or embryos—limits on number of families - Section 40 (1) (c)

This clause substitutes section 40(1)(c). This amendment is intended to address a drafting error by clarifying the circumstances when the family limits outlined in subsections (c)(i) & (ii) are engaged. It clarifies that the offence at section 40 is engaged when an ART provider provides ART treatment, and that ART treatment would result in the family limits outlined in subsections (c)(i) & (ii) being breached if a child were to born as a result of that ART treatment.

This is intended to clarify that the prohibition in section 40 applies to the creation of additional families using donated gametes from the same donor. It does not limit families already created within the family limits from having more children using the same donor.

# Clause 5 Mandatory information - Section 53 (2) (a)

This clause amends section 53(2)(a) to clarify that the list of information about the donor under subsection (2)(a) refers to the information that an ART provider must already keep as a record under section 48.

The purpose of this clause is to clarify that when providing the list of information to the director-general under section 53(2), the section does not require an ART provider to 'refresh' or 'recollect' the list of information.

# Clause 6 Protection of public officials from liability - New section 121 (3)

This clause inserts a defined term for 'public official'. It provides that a public official is the director-general, or an authorised person, or a person exercising a function under this Act, but does not include an ART provider.

#### Clause 7 Section 128

This clause substitutes section 128. It replaces the previous heading of section 128 'Meaning of *transitional period* – pt 12' and updates the heading to 'Definitions – pt 12'.

This clause also inserts two further definitions into section 128 to define the terms 'basic provisions' and 'extended provisions'. The purpose of these new defined terms is to reformat the transitional provisions (Part 12 of the Assisted Reproductive Technology Act 2024) to improve the readability of the legislation. The basic provisions and extended provisions mirror the list of provisions disapplied at section 131(3)(c) and (3)(b) of the Assisted Reproductive Technology Act 2024 respectively.

For the purposes of Part 12 of the *Assisted Reproductive Technology Act 2024*, the *basic provisions* are:

- section 39 (Donated gametes or embryos—time limits on use); and
- section 40 (Donated gametes or embryos—limits on number of families); and
- section 53 (Mandatory information).

For the purposes of Part 12 of the *Assisted Reproductive Technology Act 2024*, the *extended provisions* are:

- section 39 (Donated gametes or embryos—time limits on use); and
- section 40 (Donated gametes or embryos—limits on number of families); and
- section 53 (Mandatory information); and
- section 46 (Requirement to collect information about gamete provider); and
- section 47 (Requirement to collect information about person undergoing ART treatment); and
- section 48 (Requirement to keep records).

This clause does not amend the definition of transitional period under section 128.

#### Clause 8 Sections 131 and 132

This clause amends section 131 and 132. It also inserts five new sections:

- new section 132A;
- new section 132B;
- new section 132C;
- new section 132D;
- new section 132E.

<u>Amendments to section 131 - Completion of family—subsequent gametes where</u> person became pregnant before end of transitional period

This clause substitutes section 131. It replaces the previous heading of section 131 'Completion of family – gametes donated before end of transitional period' and updates the heading to 'Completion of family – subsequent gametes where person became pregnant before end of transitional period'.

This clause also amends section 131 in two ways. First, it removes the requirement that a gamete must be donated prior to the end of the transitional period for the gamete to be used under section 131. The purpose of this amendment is to allow the use of additional gametes sourced from the same donor which will enable a person to complete their family.

Second, this clause removes the staged approach under subsections (3)(b) and (c) which disapplied a longer list of provisions if a person became pregnant before the transitional period, and a shorter list of provisions if a person became pregnant during the transitional period. Instead, the amended section 131 disapplies the longer list of provisions – the *extended provisions* (see clause 7) – if a person became pregnant before the end of the transitional period. The purpose of this amendment is to ensure that people who became pregnant prior to 28 September 2024 are able to use gametes from the same donor to have subsequent pregnancies and be exempted from the *extended provisions*.

Section 131 is intended to apply to a person who becomes pregnant before the end of the transitional period, irrespective of whether that first pregnancy results in the birth of a child (that is, section 131 will apply to a person irrespective of whether the pregnancy ends in miscarriage or still birth).

Amendments to section 132 - Completion of family—embryos created before end of transitional period

This clause substitutes section 132. This clause amends section 132 by removing the staged approach under subsections (3)(b) and (c) which disapplied a longer list of provisions if an embryo was created before the transitional period, and a shorter list of provisions if an embryo was created during the transitional period. Instead, the amend section 132 disapplies the longer list of provisions – the *extended provisions* (see

clause 7) – if the embryo was created before the end of the transitional period. The purpose of this amendment is to ensure that people who have already created embryos prior to 28 September 2024 are able to use those embryos in ART treatment and be exempted from the *extended provisions*.

# New section 132A - Completion of family—subsequent gametes where embryo created before end of transitional period

New section 132A provides that under certain circumstances, an ART provider may use another donated gamete from a donor (a *subsequent gamete*) in the provision of ART treatment to a person or their domestic partner (or to create an embryo for use in the provision of ART treatment to the person or their domestic partner) and the *extended provisions* (see clause 7) will not apply to that use. The circumstances are:

- 1. an embryo from the same donor was created from a donated gamete before the end of the transitional period (i.e. before 28 September 2024) for use in the provision of ART treatment to the person; and
- 2. the person or their domestic partner becomes pregnant as a result of ART treatment using the embryo.

The purpose of new section 132A is to ensure that if a person or their domestic partner has become or becomes pregnant using embryos created prior to the end of the transitional period, they will be exempt from the *extended provisions* (see clause 7) for subsequent use of the donor's gametes. This allows individuals to complete their families with genetically related children.

Section 132A is intended to apply to a person who becomes pregnant using the relevant embryos that have been created before the end of the transitional period, irrespective of whether that first pregnancy results in the birth of a child (that is, section 132A will apply to a person irrespective of whether the first pregnancy ends in miscarriage or still birth).

# New section 132B - Completion of family—gametes donated and allocated before end of transitional period

New section 132B provides an ART provider may use a donated gamete that was allocated to a particular person before the end of the transitional period to provide ART treatment to that person or their domestic partner. The ART provider may also use that gamete to create an embryo for use in the provision of ART treatment to the person or their domestic partner.

The ART provider is exempt from the *extended provisions* (see clause 7) when using the gamete if the gamete was allocated before the transitional period (i.e. before 29 March 2024).

The ART provider is exempt from the *basic provisions* (see clause 7) when using the gamete if the gamete was allocated during the transitional period (i.e. between 29 March 2024 and 27 September 2024).

New section 132B(4) also defines two circumstances where a donated gamete is considered to be *allocated* to a particular person:

- 1. if the gamete has been obtained by the person, or an ART provider, for the purpose of providing ART treatment to the person or their domestic partner; or
- 2. if the gamete is held in storage and an arrangement is in place for it to be given to the person, or an ART provider, for the purpose of providing ART treatment to the person or their domestic partner.

It is not intended for a gamete to be *allocated* if the gamete was sourced directly by an ART provider and was not allocated to a specific client. That is, a gamete acquired as part of a bulk acquisition to generally supply gametes across the ART provider's client base would not be considered an *allocated* gamete for the purposes of this clause.

# New section 132C - Completion of family—subsequent gametes where gamete allocated before end of transitional period

New section 132C provides that under certain circumstances, an ART provider may use another donated gamete from a donor (a *subsequent gamete*) in the provision of ART treatment to a person or their domestic partner (or to create an embryo for use in the provision of ART treatment to the person or their domestic partner) and either the *extended provisions* or the *basic provisions* (see clause 7) will not apply to that use. The circumstances are:

- 1. a donated gamete from the same donor was allocated to a particular person before the end of the transitional period (i.e. before 28 September 2024) (the *first gamete*); and
- 2. the person or their domestic partner becomes pregnant as a result of ART treatment using the *first gamete*.

The ART provider is exempt from the *extended provisions* (see clause 7) when using a *subsequent gamete* if the *first gamete* was allocated before the transitional period (i.e. before 29 March 2024).

The ART provider is exempt from the *basic provisions* (see clause 7) when using a *subsequent gamete* if the *first gamete* was allocated during the transitional period (i.e. between 29 March 2024 and 27 September 2024).

The purpose of new section 132C is to ensure that if a person or their domestic partner has become or becomes pregnant using gametes allocated prior to the end of the transitional period, they will be exempt from certain provisions for subsequent use of

the donor's gametes. This allows individuals to complete their families with genetically related children.

Section 132C is intended to apply to a person who becomes pregnant using gametes allocated in the relevant period, irrespective of whether that first pregnancy results in the birth of a child (that is, section 132C will apply to a person irrespective of whether the first pregnancy ends in miscarriage or still birth).

New section 132D - Donor taken to consent to use of gametes and embryos for completion of family

New section 132D provides that for donated gametes or embryos created from donated gametes used in accordance with section 131 132, 132A, 132B, or 132C, the donor is taken to have consented to the use and may modify or withdraw consent in accordance with section 30 of the *Assisted Reproductive Technology Act 2024*.

# New section 132E - Certain things done or omitted to be done not invalid

New section 132E provides that something is taken to have been validly done or omitted to be done if:

- 1. before the commencement day of this clause (i.e., the day after this Act's notification day (see clause 2)), the ART provider has done or omitted to do something; and
- 2. on or after the commencement day of this clause, the ART provider could have validly done or omitted to do the thing under section 131 132, 132A, 132B, or 132C.

This is new section is intended to mitigate any issues which arise because of the introduction of the new transitional arrangements under the Act after the original commencement of the Assisted Reproductive Technology Act 2024.